REMARKS

Reconsideration of the above-identified application in view of the amendment above and the remarks below is respectfully requested.

No claims have been canceled or added in this paper. Claims 34 and 41 have been amended in this paper. Therefore, claims 2-10 and 34-48 are pending and are under active consideration.

As best understood by Applicant, claims 34-48 stand rejected under 35 U.S.C. 112, second paragraph. In apparent support of the rejection, the Patent Office states the following:

> The term "substantially enantiomerically pure" in claims 34-48 is a relative term which renders the claim indefinite. The term "substantially enantiomerically pure" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Particularly, it is not clear what is encompassed by the term "substantially".
>
> The term "such as" in claims 34-41 is a relative term which renders the claim indefinite. The term "such as" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear if the term "such as" limits the scope of the disease to the list provided in the claims or if other, not listed disease, are included.

Applicant respectfully traverses the subject rejection.

Insofar as the subject rejection relates to the recitation of the term "substantially enantiomerically pure" in claims 34, 35, 41, and 42 (claims 36-40 not reciting "substantially enantiomerically pure" but apparently being included in the rejection by virtue of depending from claim 35 and claims 43-48 not reciting "substantially enantiomerically pure" but apparently being included in the rejection by virtue of depending from claim 43), Applicant respectfully disagrees that

"substantially enantiomerically pure" is indefinite. Applicant respectfully submits that a person of ordinary skill in the art would understand the meaning of "substantially enantiomerically pure," as evidenced, for example, by the fact that this term has appeared in nearly 50 issued U.S. patents (see attached printout of search results for patents having claims that include the term "substantially enantiomerically pure"). It is well-established that the appearance of a claimed term in a number of issued U.S. patents is highly probative of the term's definiteness. The aforementioned U.S. patents include patents covering compounds in use as active pharmeutical ingredients (e.g., U.S. Patent No. 5,428,159: galanthamine), in which a person of ordinary skill would interpret "substantially enantiomerically pure" in accordance with the corresponding requirements of the US Pharmacopoeia. Therefore, for at least the reason that this term has appeared in nearly 50 issued U.S. patents, Applicant respectfully submits that the term is definite.

Insofar as the subject rejection relates to the recitation of the term "such as" in claims 34 and 41 (claims 35-40 not reciting "such as" but apparently being included in the rejection by virtue of depending from claim 34), Applicant notes that the term "such as" no longer appears in the claims. Therefore, this basis for the rejection is no longer applicable.

Finally, Applicant wishes to point out that the terms "substantially enantiomerically pure" and "such as" have appeared in the claims of the present application for quite some time. In fact, claim 34 has recited "such as" ever since the present application was first filed, and no issue regarding this term had been raised by the Patent Office in five previous Office Actions prior to the outstanding Office Action. In addition, claims 34, 35, 41, and 42 have recited "substantially enantiomerically pure" since as early as June 18, 2009, and no issue regarding this term had been

raised by the Patent Office in the Office Action prior to the outstanding Office Action. There is no apparent reason why these issues are now being raised at this stage in prosecution.

Accordingly, for at least the above reasons, the subject rejection should be withdrawn.

In view of the fact that claims 34-40 are rejected solely on the basis of 35 U.S.C. 112, second paragraph, and further in view of the fact that said rejection should be withdrawn for at least the reasons given above, Applicant respectfully submits that claims 34-40 should be immediately allowed.

Claims 2-6 and 41-48 stand rejected under 35 U.S.C. 103(a) "as being unpatentable over Chesi (US 5,017,607) in view of Dyck (Journal of Neurochemistry 1986, 46(2), pp 399-404), Ando et al. (US 6,603,008), Foster (US 6,221,335), Tonn et al. (Biological Mass Spectrometry 1993, 22(11), pp 633-642), Haskins (Biomedical Spectrometry 1982, 9(7), pp 269-277), Wolen (Journal of Clinical Pharmacology 1986; 26, pp 419-424; abstract), Keinan et al (US 6,440,710) and Gouyette (Biomedical And Environmental Mass Spectrometry, 1988, 15, pp 243-247)."

Applicant respectfully traverses the subject rejection. As best understood by Applicant, the Patent Office appears to be taking the position that (i) that Chiesi teaches the claimed compound and the claimed method, except for the claimed deuteration; (ii) that, in view of Dyck, Ando et al. and Foster, one of ordinary skill in the art would have been "motivated to prepare deuterated versions of drugs to obtain a version with better pharmaceutical properties"; and (iii) that, in view of Tonn et al., Haskins, Wolen, Keinan et al., and Gouyette et al., one of ordinary skill in the art would have been "motivated to prepare deuterated versions of drugs, which can be used to obtain valuable information

about how the undeuterated drug or closely related drugs act in the body." Applicant respectfully disagrees with the Patent Office for at least the reasons below.

It is well-settled that the prior art must provide a person of ordinary skill in the art with some specific guidance or direction to modify the prior art in such a way as to arrive at the claimed invention. Applicant respectfully submits that no such guidance or direction is provided in the present rejection. Chiesi, as apparently acknowledged by the Patent Office, is completely silent on the topic of deuteration of its levodopa methyl ester. None of the secondary references relied upon by the Patent Office provides any specific guidance or direction to deuterate at the particular positions required by the present claims. Instead, all that the secondary references provide are non-specific comments about alleged benefits of deuteration. However, as has been pointed out by Applicant in his responses of March 2, 2010, and June 15, 2007, the substitution of L-DOPA with deuterium at different positions leads to unpredictable results. (Applicant is willing to provide the results of the aforementioned responses in the form of a declaration if the Patent Office so desires.) "Unpredictable" means an improvement, no change, or a reduction in utility relative to the non-deuterated progenitor. Mono-deuteration in the alpha position of L-DOPA or di-deuteration in the beta positions gives a reduced striatal level of deuterated dopamine relative to dopamine. There is, therefore, no further incentive to explore deuteration as a strategy to modify L-DOPA -- one might actually expect tri-deuteration to give an additive effect of alpha and beta modification, whereas it actually reverses the trend. L-DOPA is a pro-drug that requires enzymatic processes to be useful. Kushner et al. (of record, p.83 thereof) points out that deuteration of drugs that need to be metabolically activated like L-DOPA can reduce their effectiveness. The applicant can prove that

exactly this was the case for mono-deuteration in the alpha position of L-DOPA or di-deuteration in the beta positions, whereas, by contrast and surprisingly, alpha,beta,beta deuterated L-DOPA enhanced. the striatal output of dopamine.

Therefore, in view of the unpredictable effects of deuteration at different positions, references that merely disclose deuteration in general or that disclose non-specific benefits of deuteration, without providing any specific teaching to deuterate the compound of Chiesi at particular positions, do not provide the type of specific guidance or direction necessary to modify the prior art to arrive at the claimed invention.

Accordingly, for at least the above reasons, the subject rejection should be withdrawn.

Claims 2-5, 7-10 and 41-48 stand rejected under 35 U.S.C. 103(a) "as being unpatentable over Milman et al (US 5,525,631) in view of Dyck (Journal of Neurochemistry 1986, 46(2), pp 399-404), Ando et al. (US 6,603,008), Foster (US 6,221,335), Tonn et al. (Biological Mass Spectrometry 1993, 22(11), pp 633-642), Haskins (Biomedical Spectrometry 1982, 9(7), pp 269-277), Wolen (Journal of Clinical Pharmacology 1986; 26, pp 419-424; abstract), Keinan et al (US 6,440,710) and Gouyette (Biomedical And Environmental Mass Spectrometry, 1988, 15, pp 243-247)."

Applicant respectfully traverses the subject rejection for analogous reasons to those discussed above in connection with the previous rejection.

Accordingly, for at least the above reasons, the subject rejection should be withdrawn.

In conclusion, it is respectfully submitted that the present application is in condition for allowance. Prompt and favorable action is earnestly solicited.

If there are any fees due in connection with the filing of this paper that are not accounted for, the Examiner is authorized to charge the fees to our Deposit Account No. 11-1755. If a fee is required for an extension of time under 37 C.F.R. 1.136 that is not accounted for already, such an extension of time is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

Kriegsman & Kriegsman

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Dated: November 5, 2010

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on November 5, 2010.

_____

Edward M. Kriegsman
Reg. No. 33,529
Dated: November 5, 2010

USPTO Patent Full-Text and Image Database

Searching US Patent Collection...

Results of Search in US Patent Collection db for:
ACLM/"substantially enantiomerically pure": 48 patents.
*Hits **1** through **48** out of **48***

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Refine Search aclm/"substantially enantiomerically pure"

	PAT. NO.		Title
1	7,790,436	T	Method for production of (1S)-3-chloro-1-(2-thienyl)-propan-1-ol using alcohol dehydrogenase from thermoanaerobacter
2	7,598,261	T	Spirocyclic heterocyclic derivatives and methods of their use
3	7,371,903	T	2-butanol production method
4	7,361,689	T	Antibacterial 1-(4-mono- and di-halomethylsulphonylphenyl)-2-acylamino-3-fluoroproponals and preparation thereof
5	7,348,356	T	Phenylcarboxamide beta-secretase inhibitors for the treatment of Alzheimer's disease
6	7,256,302	T	Substituted paracyclophane derivatives in asymmetric catalysis
7	7,214,834	T	Process for preparing enantiomerically pure 1,1'-spirobiindane-6,6'-diol derivatives
8	7,169,793	T	Process for preparation of optically pure or optically enriched sulfoxide compounds, including amorphous esomeprazole and salts thereof
9	7,153,842	T	Florfenicol prodrug having improved water solubility
10	7,109,217	T	Phenylcarboxamide beta-secretase inhibitors for the treatment of Alzheimer's disease
11	7,041,670	T	Florfenicol-type antibiotics
12	7,038,063	T	Atropisomers of asymmetric xanthene fluorescent dyes and methods of DNA sequencing and fragment analysis
13	6,939,981	T	Ruthenium complexes of phosphine-aminophosphine ligands
14	6,908,752	T	Process for the preparation of the enant iomeric forms of 2-substituted 2- (2, 5-dioxoimidazolidin-1yl) -acetic acid derivatives
15	6,906,213	T	Preparation of aminophosphines
16	6,906,212	T	Phosphine-phosphoramidite compounds
17	6,699,495	T	Methods for treating multiple sclerosis employing desmethylselegiline
18	6,686,477	T	Highly enantiomerically pure lactam-substituted propanoic acid derivatives and methods of making and using same

19 6,683,220 T Process for the preparation of optically pure or enriched racemic tetralone
20 6,635,784 T Process for the preparation of enantiomerically-enriched cyclopropylalanine derivates
21 6,620,954 T Phosphinometallocenylamides as novel ligands for asymmetric catalysis
22 6,590,115 T Phosphino-aminophosphines
23 6,562,365 T Methods employing R(-)-desmethylselegiline
24 6,551,816 T Enzymatic method for preparing synthesis intermediates
25 6,528,082 T Methods and pharmaceutical compositions employing desmethylselegiline to treat neoplastic diseases or conditions
26 6,419,948 T R(-)desmethylselegiline and its use in transdermal delivery compositions
27 6,348,208 T Methods and pharmaceutical compositions employing desmethylselegiline
28 6,340,587 T Process for preparing enantiomerically enriched N-derivatized lactams
29 6,268,533 T Formoterol process
30 6,251,950 T Aliphatic propargylamines as cellular rescue agents
31 6,207,854 T Preparation of 3-amino-3-cyclopropylpropanoate esters
32 6,140,516 T Process for the preparation of trans-3-alkyloxy-4-hydroxytetrahydrofuran
33 6,103,929 T Process for the preparation of cyclopropylglycine
34 6,037,505 T Enantioselective oxazaborolidine catalysts
35 6,037,498 T Chiral syntheses
36 6,005,133 T Enantioselective oxazaborolidine catalysts
37 5,997,840 T Chiral solid catalyst, its preparation and its use for the production of substantially enantiomerically pure products
38 5,948,909 T Process for the stereoselective preparation of a hetero-bicyclic alcohol enantiomer
39 5,801,249 T Chiral auxiliaries
40 5,801,248 T Stereoselective syntheses
41 5,777,138 T Ring-opening amidation process
42 5,599,969 T Process of resolving phenylpropionic acids using .alpha.-methylbenzylamine
43 5,552,548 T Enantioselective oxazaborolidine catalysts
44 5,539,130 T 7-Oxabicycloheotane carboxylic acid prostaglandin analog intermediates useful in the preparation of anti-thrombotic and anti-vasospastic compounds and method for preparing same
45 5,512,690 T 7-oxabicycloheptane carboxylic acid prostaglandin analog intermediates useful in the preparation of anti-thrombotic and anti-basopastic compounds and method for preparing same
46 5,428,159 T Method of manufacture of (-)-galanthamine in high yield and purity substantially free of epigalanthamine
47 5,053,512 T Total synthesis of 20(S) and 20(R)-camptothecin and compthothecin derivatives
48 4,880,738 T Production of amino acids using coupled enzyme systems

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